CALIFORNIA CABG OUTCOMES REPORTING PROGRAM (CCORP) CLINICAL ADVISORY PANEL (CAP)

Los Angeles Airport Marriott 5855 West Century Blvd. Los Angeles, CA

March 6, 2007 9:30 a.m. to 3:00 p.m.

MEETING MINUTES

In Attendance

Clinical Advisory Panel Members: OSHPD:

Robert Brook, M.D., Sc.D. Holly Hoegh, Ph.D.

Ralph Brindis, M.D., F.A.C.C.

Denise King Timothy Denton, M.D., F.A.C.C.

Victor Muh

Coyness Ennix, Jr., M.D.

Keith Flachsbart, M.D.

Joseph Parker, Ph.D.

Thomas Reiner, Ph.D.

James MacMillan, M.D. Elizabeth Wied, Chief Counsel

Other Attendees:

Joe Carey, M.D., CA Society of Thoracic Surgeons Richard Kravitz, M.D., M.S.P.H., UC Davis Zhongmin Li, Ph.D., Health Services Researcher, UC Davis Anthony Steimle, M.D., CCORP Consulting Cardiologist

Introduction

Dr. Robert Brook, Chairman, called the meeting to order at 9:30 a.m. After introductions there was a motion by Dr. Ralph Brindis to approve the minutes from the last meeting and Dr. Keith Flachsbart seconded the motion. All were in favor. Dr. Joseph Parker delivered the Program Director's Report.

The 2003-2004 hospital and surgeon report is complete and in the process of administrative review by Agency and will also go to the Governor's Office for review. Expected release is in May. Report includes hospital level results for 2003-2004 combined and 2004 separately and surgeon level results for 2003-2004 combined. It also includes IMA usage rates by hospital for 2003-2004. Report shows no statistically significant effect of hospital volume on outcome. For surgeon effect, only one of several tests showed a significant relationship.

The first six months of 2006 data is in. Second six months of data is due on April 2 with extension and resubmission days extending the final acceptance date by more than one month. OSHPD is considering regulatory changes to speed up this process. This is the first year where information is being collected on complications, as well as pre-op resuscitation and radial artery usage.

CABG numbers continue to decrease. Less than 17,000 are expected in 2006 based on 6 months annualized data. PCI numbers have stabilized the last 3 years at about 60,000/yr. Total isolated CABG surgeries per hospital is less than 140/year. Non-isolated CABG surgeries have increased slightly, from an average of 37 to 39/year.

Complications that are included in the 2006 data: prolonged ventilation, coma, deep sternal wound infection, reop for bleeding, reop for graft occlusion, stroke, and renal failure monitored. Panel discussed complications measures, including which to include in a public report and develop risk models for first. They also discussed the possibility of using a combined measure. UCD contractors are responsible for the complications analyses and are looking at stroke and renal failure first as they appear to be the most accurately reported by hospitals.

Dr. Parker discussed the option of collecting more process measures (in addition to IMA usage), especially those that have been endorsed by the National Quality Forum (Pre-op beta blocker in patients with isolated CABG, Anti-platelet medication on discharge, and Beta blocker on discharge).

OSHPD legal counsel has recommended that OSHPD not pursue the collection of more process measures, since the program's mandate refers only to risk-adjusted outcomes. Panel discussed importance of collecting and reporting on process measures. Dr. Coyness Ennix moved that the process measures from the National Quality Forum be included by CCORP and that Dr. Parker recommend this to Dr. David Carlisle. Dr. Timothy Denton seconded the motion and all approved.

Dr. Parker discussed the upcoming hospital level report. There was a discussion by the panel of the state contract process and how it contributes to program delays. Dr. Parker clarified that more than anything; it is the availability of the State Death file from the Department of Health Services that holds up the reports.

Panel discussed the problems with acquiring the death file and use of risk-adjusted in-hospital mortality (as opposed to operative mortality) in selecting the audit sample and for the outcomes report. Dr. Brook moved that the selection of hospitals for the audit be done on in-patient mortality. Dr. Ennix seconded the motions and all were in favor. It was decided that operative mortality would remain the measure for the public reports.

CCORP discussed changing program regulations to require earlier submission of data by hospitals to speed up public reporting. The Committee strongly supported any reasonable approach to speeding up the issuance of public reports.

Dr. Parker and Panel discussed the hierarchical approach to risk-modeling. Dr. Brook requested a presentation that would compare the size of the confidence intervals between low- and middle-volume surgeons in the logistic model. There was further discussion of risk models and low volume surgeons. Panel opted to stay with the logistic regression method of modeling but continue to perform a hierarchical analysis on an ongoing basis.

Dr. Parker brought up the issue of years of data to be included in the next hospital level report. Correlation of year to year outcomes was presented. 2003-2004 data correlated year to year, but not very well with 2005 data. Data from 2004 correlated better with 2005 data. Panel discussed the possibility of reporting on surgeons every year. They decided to keep the next report as hospital only, but revisit the issue in the future. Dr. Ennix motioned that the next hospital level report include 2005 data only. Dr. Denton seconded the motion and all were in favor. A graphic

example of trends from the CCMRP report was presented and discussed. Dr. Keith Flachsbart motioned that a graphic display of multiple years of data by hospital be included in the report. Dr. Ennix seconded and all were in favor. UCD will see if standard deviations around the point estimates of risk-adjusted mortality can be included.

A discussion of the volume outcomes analysis led to a motion by Dr. Ralph Brindis to keep this analysis in the report. Dr. Denton seconded the motion and all were in favor.

IMA usage was discussed. It was noted that IMA usage had increased in 2005-2006 compared to 2003-2004, after collection of usage rates began. Dr. Flachsbart motioned that IMA usage rates be included in the 2005 report. All approved.

The inclusion of new CCORP data elements was discussed. The statute allows up to six new elements not in the STS database to be added every five years. New elements would likely not be in effect until 2009. Dr. Parker suggested that risk factors be considered in three areas: liver disease, non-isolated CABG mortality, and which vessel bypassed in CABG surgery. Dr. Steimle explained that the current definition for hepatic failure is very strict and most patients with liver disease cannot meet the definition. Further discussion noted that liver failure is an important risk factor and that perhaps a better element can be developed. It was suggested that Dr. Parker send out a note to the Panel members asking them to report up to six additional non-STS risk factors that could be added. OSHPD will also present possible modifications to the liver failure risk factor at the next meeting.

The panel discussed the possibility of adding data elements necessary to create a risk model for non-isolated CABG. It was pointed out that SB 680 requires reporting on all CABG surgeries, not just isolated. Dr. Parker noted that non-isolated CABG was 12% of all CABG surgeries in 2000 and now is 26% of total CABG volume. Dr. Denton made a motion to have CCORP move forward with development of a non-isolated CABG risk model, which will likely require collection of additional data elements. Dr. Flachsbart seconded the motion and all approved.

Dr. Parker asked for discussion on the issue of adding a data element for which vessel was bypassed in surgery. This would be used to get information about the LAD, and whether the IMA could have been used or was used appropriately. Dr. Brook suggested that Dr. Parker send an email to the panel members asking if they have suggestions on how Dr. Amsterdam should approach creation of such a data element.

Dr. Kravitz of UC Davis presented a report on appropriateness in CABG surgery. A measure was used to study the % of "survival enhancing indications" for CABG cases by hospital and surgeon. Approximately 70% of 2003-2004 CABG cases were performed for SEI. This number varied widely by surgeon and hospital. The number did not vary with risk adjusted outcome. A logistic regression analysis found that teaching hospitals, older age and Hispanic ethnicity were associated with higher SEI. The study suggested that SEI was not a definitive measure for appropriateness. Dr. Kravitz will deliver his final report to OSHPD and continue with work on a proposal to move forward in this area of research.

Dr. Anthony Steimle discussed clarifications for Ventriculectomy as an exclusion in the Isolated CABG Definition. Dr. Ennix moved that Ventricular rupture will only meet the Non-isolated CABG definition if diagnosed preoperatively as a rupture, aneurysm or remodeling procedure. All were in favor. Other ventricular repairs will be considered isolated CABG surgeries: 1) sites intra-operatively diagnosed during surgery, 2) patch applications for site oozing, 3) prophylactic

patch applications to reduce chances of future rupture. OSPHD will determine if regulatory changes are needed.

Dr. Hoegh presented a review of the surgeon statement review process. Panel discussed their thoughts on the data submission process and the surgeon statement process. Dr. Brook requested a handbook specifically for surgeons be created that explained the data collection and surgeon statement review process. There was brief discussion of possible regulatory clarifications, but no action item was specified.

There was a discussion of whether to exclude all Salvage cases either overall or at the surgeon level. Dr. Brindis made a motion to exclude salvage cases when reporting risk-adjusted results by surgeon, but to include them in hospital reports. Dr. Ennix seconded the motion and all were in favor. Documentation from hospitals would be required for Salvage cases (e.g., op report). Timing for implementation requires program review. OSHPD will prepare a bulletin for release to hospitals and surgeons.

Dr. Hoegh also mentioned the issue of excluding cases based on a combination of risk factors that make the patient a very high mortality risk. The panel found this approach unworkable.

Dr. Hoegh presented some possible regulatory changes that could be implemented to refine the data collection and review process, including changing the submission date for hospitals to 45 days after each six month period instead 60. Dr. Brook emphasized the importance of the communications process between OSHPD and the hospitals and surgeons.

There was a period of public comment. Dr. Joseph Carey discussed the California Cardiac Surgeon Intervention Project and asked about the composition of the Clinical Advisory Committee. The meeting was adjourned.